General

Guideline Title

Common breast problems.

Bibliographic Source(s)

University of Michigan Health System. Common breast problems. Ann Arbor (MI): University of Michigan Health System; 2013 Jun. 11 p. [10 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Common breast problems. Ann Arbor (MI): University of Michigan Health System; 2007 Oct. 10 p. [7 references]

Recommendations

Major Recommendations

Note from the University of Michigan Health System (UMHS) and the National Guideline Clearinghouse (NGC): The following guidance was current as of June 2013. Because UMHS occasionally releases minor revisions to its guidance based on new information, users may wish to consult the original guideline document for the most current version.

Note from NGC: The following key aspects and recommendations summarize the content of the guideline. Refer to the full text for detailed information on each of the screening procedures.

The strength of recommendation (I-III) and levels of evidence (A-D) are defined at the end of the "Major Recommendations" field.

Key Aspects and Recommendations

Palpable Mass or Asymmetric Thickening/Nodularity on Physical Exam

Discrete masses elevate the index of suspicion. Physical exam cannot reliably rule out malignancy.

- Breast imaging is the next diagnostic approach to aid in diagnosis *[I C]*.
- Initial imaging evaluation: if age ≥30 years then mammogram followed by breast ultrasound; if age <30 years then breast ultrasound *[I C]*. Follow-up depends on results (see Figure 1 of the original guideline document).

Asymmetrical thickening/nodularity has a lower index of suspicion, but should be assessed with breast imaging based on age as for patients with a

discrete mass. If imaging is:

- Suspicious or highly suggestive (Breast Imaging Reporting and Data System [BI-RADS] category 4 or 5) or if the area is assessed on clinical exam as suspicious, then biopsy after imaging *[I C]*. Referral to a breast care specialist may be useful.
- Probably benign (BI-RADS 3): if clinically benign, observe every 3–6 months and image every 6–12 months for 2 years to assess stability *[I C]*; if clinically suspicious, biopsy tissue *[I C]*.
- Negative or benign (BI-RADS 1 or 2): if clinically benign, then follow-up physical exam in 3 months *[I C]*, if clinically suspicious, biopsy tissue *[I C]*. Simple cysts (Benign finding, BI-RADS 2) need aspiration only if symptomatic. *[I C]*.

Referral to breast care specialist is also recommended for: (a) any suspicious mass or (b) any woman at very high risk for breast cancer *[I D]*.

Inflammation and Other Skin Changes

If cellulitic breast skin changes:

- Do not completely resolve after a course of antibiotics, refer to a breast specialist for consideration of breast biopsy to rule out inflammatory breast cancer *[I C]*.
- Are associated with a fluctuant, painful mass, refer to a breast specialist or emergency department for management of a possible breast abscess *[I C]*.

If eczematoid changes of the nipple-areolar skin persist >1-2 weeks or do not respond to topical treatment, refer to a breast specialist for possible biopsy to rule out Paget's disease of the nipple *[I C]*.

Breast Pain With Negative Physical Exam (see Figure 2 in the original guideline document)

- If physical exam and appropriate breast imaging are negative, the likely diagnosis is benign mastalgia: reassure patient. A trial of topical agents is reasonable (see text of the original guideline document) *[II A]*. Recommendation for a well-fitted bra is often helpful *[II C]*.
- If persistent or localized pain not responsive after 2-3 months of conservative treatment, refer to breast specialist *[I C]*.

Nipple Discharge Without Abnormal Exam Findings (see Figure 3 in the original guideline document)

- If discharge is spontaneous or watery/serous or if other risk factors are present (persistent, serosanguinous, single duct), refer to a breast specialist and consider diagnostic imaging *[I C]*.
- If discharge is non-spontaneous, if clearly galactorrhea, pursue medical workup and do not refer to breast specialist *[I C]*. If discharge is from multiple ducts and gray to green in color, do not refer to a breast specialist unless patient requests referral for symptomatic relief *[I C]*.

Special Populations

Pregnant women. If concerning indications, imaging is relatively safe and should be done *[I C]*.

Men. Diagnose and treat enlargement or pain *[I C]*. Breast mass is rare, but suspicious for cancer *[I C]*.

Augmented breasts. Evaluation/management of above conditions is similar, but imaging issues *[I C]*.

Definitions:

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Strength of Recommendation

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Clinical Algorithm(s)

The following algorithms are provided in the original guideline document:

- Palpable Breast Mass or Asymmetric Thickening/Nodularity: Diagnosis and Treatment
- Breast Pain Diagnosis and Treatment
- Nipple Discharge Diagnosis and Treatment (no mass)

Scope

Disease/Condition(s)

Common breast problems:

- Palpable mass or asymmetric thickening/nodularity on clinical exam
- Inflammation and other skin changes
- Breast pain with negative exam
- Nipple discharge without abnormal exam findings

Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Screening

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Radiology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To identify appropriate evaluation and management strategies for common breast problems
- To identify appropriate indications for referral to a breast specialist

Target Population

Adults age 18 and older

Interventions and Practices Considered

Diagnosis/Evaluation/Risk Assessment/Screening

1. Physical exam
2. Diagnostic imaging:
    - Mammography
    - Ultrasound
    - Magnetic resonance imaging (as an adjunct screening method for high-risk women)
3. Biopsy
4. Fine needle aspiration (FNA)
5. Risk assessment (Breast Imaging Reporting and Data System [BI-RADS])

Management/Treatment

1. Pharmacologic treatment for breast pain including evening of primrose oil, diclofenac gel, non-steroidal anti-inflammatory drugs (NSAIDs), and hormonally active medicines including tamoxifen, danazol, gonadotrophin releasing hormone analogs and bromocriptine
2. Referral to breast specialist or emergency department as indicated
3. Antibiotics
4. Nonpharmacologic interventions to reduce breast pain, such as a well-fitting bra, relaxation techniques, warm compresses or cold packs, gentle massage
5. Management of special populations:
    - Pregnant women
    - Men
    - Augmented breasts

Major Outcomes Considered

- Positive predictive value, sensitivity and/or specificity of diagnostic tests
- Incidence of breast cancer

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The literature searches for this update began with the results of the literature searches performed for the earlier version of this guideline through June 2005. For this update the Breast Cancer Screening and Diagnosis Guidelines of the National Comprehensive Cancer Network (2012) and its supporting literature through early 2012 was used to address the topics of: palpable mass, asymmetric thickening/nodularity, inflammation and other skin changes, breast pain. To supplement that literature, searches in MEDLINE were performed. For the major keywords of adult women; since 6/1/2005; English language; and guidelines, controlled trials (including meta-analyses), and cohort studies; specific searches were performed for breast pain, galactorrhea and other nipple discharge, and breast mass in pregnancy. For the major keywords of adult men; since 6/1/2005; English language; and guidelines, controlled trials (including meta-analyses), and cohort studies; specific searches were performed for breast mass

or pain.

The searches were supplemented with recent clinical trials known to expert members of the panel. The search was single cycle.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data. If randomized clinical trials were not available, observational studies were admitted to consideration. If no such data were available, expert opinion was used to estimate effect size.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

I. Generally should be performed
II. May be reasonable to perform
III. Generally should not be performed

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Drafts of this guideline were reviewed in clinical conferences and by distribution for comment within departments and divisions of the University of Michigan Medical School to which the content is most relevant: Family Medicine, General Medicine, General Obstetrics & Gynecology, Radiology/Breast Imaging, and Surgical Oncology. The Executive Committee for Clinical Affairs of the University of Michigan Hospitals and Health Centers endorsed the final version.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Conclusions were based on prospective randomized controlled trials (RCTs) if available, to the exclusion of other data. If RCTs were not available, observational studies were admitted to consideration. If no such data were available, expert opinion was used to estimate effect size.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate evaluation and management strategies for patients who present with common breast problems

Potential Harms

- Mammography as a diagnostic tool may result in false negatives, especially in younger women. Overall, 10% of diagnostic mammograms are false negatives, with approximately twice the rate for younger women and half that rate for women over age 65.
- For evaluation of solid masses, or nonpalpable masses detected by mammography, the sensitivity of fine needle aspiration (FNA) is variable, primarily dependent on the skill of the aspirator. Estimates of false negatives range from 1% to 35% for palpable lesions and up to 68% for nonpalpable lesions.
- Side effects of hormonally active medicines tend to limit their tolerability.

Qualifying Statements

Qualifying Statements

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Patient Resources

Resources

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2007 Oct (revised 2013 Jun)

Guideline Developer(s)

University of Michigan Health System - Academic Institution

Source(s) of Funding

University of Michigan Health System

Guideline Committee

Breast Care Guideline Team

Composition of Group That Authored the Guideline

Team Leader: Monica M Dimagno, MD, General Medicine

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Financial Disclosures/Conflicts of Interest

The University of Michigan Health System endorses the Guidelines of the Association of American Medical Colleges and the Standards of the Accreditation Council for Continuing Medical Education that the individuals who present educational activities disclose significant relationships with commercial companies whose products or services are discussed. Disclosure of a relationship is not intended to suggest bias in the information presented, but is made to provide readers with information that might be of potential importance to their evaluation of the information.

None of the members of the Breast Problems Guideline Team have relationships with commercial companies whose products are discussed in this guideline.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: University of Michigan Health System. Common breast problems. Ann Arbor (MI): University of Michigan Health System; 2007 Oct. 10 p. [7 references]

Guideline Availability

Electronic copies: Available from the University of Michigan Health System Web site .

Availability of Companion Documents

The following are available:

- Continuing Medical Education (CME) information is available from the University of Michigan Health System (UMHS) Web site .
- National Cancer Institute (NCI) Breast Cancer Risk Assessment Tool. 2011 May. Electronic copies: Available from the UMHS Web site .

Patient Resources

The following are available:

- Breast pain. Ann Arbor (MI): University of Michigan Health System; 2013 Jul. 2 p. Electronic copies: Available from the University of

Michigan Health System (UMHS) Web site .

- Fibrocystic changes. Ann Arbor (MI): University of Michigan Health System; 2013 Jul. 2 p. Electronic copies: Available from the UMHS Web site .
- Galactorrhea. Ann Arbor (MI): University of Michigan Health System; 2013 Jul. 3 p. Electronic copies: Available from the UMHS Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI Institute on January 24, 2008. The information was verified by the guideline developer on February 11, 2008. This summary was updated by ECRI Institute on January 15, 2010 following the U.S. Food and Drug Administration (FDA) advisory on Voltaren Gel. This NGC summary was updated by ECRI Institute on October 21, 2013. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs).

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